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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/650,365      | 08/28/2003  | Guangwen Wei         | #792-A-PCT-US       | 7677             |

7590

09/20/2006

Albert Wai-Kit Chan  
Law Offices of Albert Wai-Kit Chan, LLC  
World Plaza, Suite 604  
141-07 20th Avenue  
Whitestone, NY 11357

EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/650,365

Applicant(s)

WEI ET AL.

Examiner

Jegatheesan Seharaseyon, Ph.D

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 38-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Continued Examination***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6 July 2006 has been entered.

### ***Status of Application, Amendments and/or Claims***

2. The amendment of 12 April 2006 has been entered in full. Claims 29-37 have been cancelled. Claims 38-47 have been added.

3. Claims 38-47 are under consideration in the instant application.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Information Disclosure Statement***

5. Applicant in exhibits (D and E) submitted 4/12/06 provides translated abstract for documents CN1217660A and CN1062565C. The Office has considered the translated abstracts only because the Examiner does not read the language of the references.

### ***Claim Objections***

5. Claim 39 is objected to because of the following informalities: The recitation "interferon of claim 38 with SEQ ID NO: 2" is not clear. It is suggested that the Applicant

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rewrite claim 39 as follows: "A recombinant super-compound interferon of claim 38 consisting of the amino acid sequence of SEQ ID NO: 2". Appropriate correction is required.

***Claim Rejections - 35 USC § 112, second paragraph maintained***

6. The rejection of claims 29-37 under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn and reapplied to pending claims 38- 47 with respect to Applicants' recitation of "super-compound interferon". The Applicants canceling of the previously pending claims do not address the rejection of record (see Office Actions dated 8/23/05, page 4 and 3/20/06, page 3).

***Claim Rejections - 35 USC § 112, second paragraph (New)***

7. Claims 38-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7a. Claim 38 recites the limitation "the primary sequence" in line 3. There is insufficient antecedent basis for this limitation in the claim. Claims 39-47 are rejected insofar as they are depend on claim 38.

7b. Claim 38 is rejected as being vague and indefinite in the recitation of the term "changed spatial configuration and higher efficacy". It is unclear what causes the change in spatial configuration and higher efficacy in the instant invention. Applicant has not provided a reference for the changes because Applicant contends that there is no

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change to the primary sequence (compared to IFN-con). Claims 39-47 are rejected insofar as they are depend on claim 38.

7c. Claim 41 is rejected as being vague and indefinite in the recitation of the term "special promoter". There is no definition in the specification of a "special promoter". One of skill in the art would not be able to determine what constitutes a special promoter from any other promoter available. Claims 42-47 are rejected insofar as they are dependent on rejected claim 41.

7d. Claim 43 is rejected as being vague and indefinite in the recitation of the term "gene". It is unclear how a protein claim can further be limited by a nucleotide-encompassing claim. Further, "gene" also lacks antecedent basis.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8a. Claims 38-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or

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chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

The claims are drawn to super-compound interferon polypeptides with changed spatial configuration and higher efficacy than IFN-con without change to the primary sequence. The claims do not require that the claimed polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. The specification teaches that super-compound interferon of SEQ ID No. 2 has identical primary sequence to IFN-con polypeptides of the prior art. However, there is no structural characteristic associated with the changed spatial configuration and higher efficacy that has been identified.

*Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The

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compound itself is required: See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1616.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the human sequence.

In this case, the only factor present in the claim is the primary sequence of super-compound interferon (SEQ ID NO: 2). There is no identification of any particular portion of the structure that is responsible for changed spatial configuration and higher efficacy. In addition, the specification does not identify the regions that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Therefore, only isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 2, but not the full breadth of the claims (changed spatial configuration and higher efficacy) meet the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

### ***Claim Rejections - 35 USC § 102***

8a. Claims 38-40 and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Stabinsky et al. U.S. Patent No. 4,695,623 or Stabinsky et al. U.S. Patent No. 4,897, 471 or Alton et al. EP422697A (Pub. Date 4/1991).

The references disclose an interferon protein sequence that is identical to the primary sequence to that of the instant invention (see Appendix A, also page1 lines 25-35 of the instant specification). The references teach interferon- $\alpha$  (human leukocyte interferon) composition. Absent evidence to the contrary it is expected that the consensus interferon of the prior art to contain identical functions to that of the instant invention. Although, not disclosed by the prior references the recombinant interferon will inherently contain the ability to inhibit DNA duplication and secretion of HBsAg and HBeAg of Hepatitis B Virus because of the increased antiviral activity. Similarly, anti-viral or anti-tumor activity are inherent to the protein. Therefore, claims 38-40 and 44-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Stabinsky et al. U.S. Patent No. 4,695,623 or Stabinsky et al. U.S. Patent No. 4,897, 471 or Alton et al. EP422697A ( Pub. Date 4/1991).

8b. Claims 38 and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Blatt et al. U.S. Patent No. 5, 372, 808.

Since Applicant asserts that the there is no change in the primary sequence, the interferon of the instant invention is considered identical to that of the prior art (column 1, lines 50-65). Blatt et al. also disclose consensus interferon in a pharmaceutical composition comprising a pharmaceutically acceptable carrier (column 4, line 24-27). The anti-viral and anti-tumor activity are also disclosed (column 4, line 15-30). Although, not disclosed by the prior references the recombinant interferon will inherently contain the ability to inhibit DNA duplication and secretion of HBsAg and HBeAg of Hepatitis B Virus because of the increased antiviral activity. Therefore, claims 38 and 44-47 are

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rejected under 35 U.S.C. 102(b) as being anticipated by Blatt et al. U.S. Patent No. 5, 372, 808.

***Claim Rejections - 35 USC § 103***

9a. Claims 38-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stabinsky et al. U.S. Patent No. 4,695,623 or Stabinsky et al. U.S. Patent No. 4,897, 471 or Alton et al. EP422697A (Pub. Date 4/1991) in view of Nasoff et al. (1999).

The teachings of Stabinsky et al. U.S. Patent No. 4,695,623 or Stabinsky et al. U.S. Patent No. 4,897, 471 or Alton et al. EP422697A (Pub. Date 4/1991) have been described above in paragraph 8a. However, the reference does not teach the interferon expression in *E. coli* under the control of pBAD promoter.

Nasoff report in Expression (April 1999), that pBAD promoter is capable of expressing high levels of the protein of the human genes in *E. coli*. pBAD promoters are tightly regulated by inducer arabinose (see pages 10 and 11 included). Therefore, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to generate the recombinant interferon described in Stabinsky et al. or Alton et al. to express the protein under *E. coli* pBAD promoter reported by Nasoff et al. The person of ordinary skill in the art would have been motivated to express the protein under the control of pBAD promoter because this will allow one of skilled in the art to efficiently express the recombinant interferons in *E. coli*. There is a reasonable expectation of success because Stabinsky et al. U.S. Patent No. 4,695,623 or Stabinsky et al. U.S. Patent No. 4,897, 471 or Alton et al. EP422697A (Pub. Date

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4/1991) have expressed the mammalian interferon protein in E.coli. Therefore, the claims 38-46 are obvious over Stabinsky et al. U.S. Patent No. 4,695,623 or Stabinsky et al. U.S. Patent No. 4,897, 471 or Alton et al. EP422697A (Pub. Date 4/1991) in view of Nasoff et al. (1999).

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10a. Claims 38-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/928,956 (US'956). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'956 discloses the same super-compound interferon of the instant invention. That is both Applications claim a recombinant super-compound interferon with changed spatial configuration and higher (improved) efficacy. In addition, US'956 also discloses that super-compound interferon is produced by a high efficiency expression system using a "special" promoters such as pBAD by along with an artificially synthesized gene (see claims 6-8 and 13). Further, it is claimed that super-compound interferon possesses anti-viral and anti-tumor activity (see claims 9-11).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art, at the time invention was made, to modify the compositions described in the US'956 to contain super-compound interferon that has the primary structure of IFN-con. Thus, one of skilled in the art would have been motivated to modify the composition to comprise the interferon (IFN-con) with reasonable expectation of success. Thus, claims 38-45 of the instant application are obvious over claims 1-13 of U.S. Application No. 10/928,956.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10b. Claims 38-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 12-17 and

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21 of copending Application No. 11/077,813 (US'813). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'813 discloses the same super-compound interferon of the instant invention. That is both Applications claim a recombinant super-compound interferon with changed spatial configuration and higher (improved) efficacy. In addition, US'813 also discloses that super-compound interferon is produced by a high efficiency expression system using a "special" promoters such as pBAD by along with an artificially synthesized gene (see claims 12-14 and 21). Further, it is claimed that super-compound interferon possesses anti-viral and anti-tumor activity (see claims 15-17).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art, at the time invention was made, to modify the compositions described in the US'956 to contain super-compound interferon that has the primary structure of IFN-con. Thus, one of skilled in the art would have been motivated to modify the composition to comprise the interferon (IFN-con) with reasonable expectation of success. Thus, claims 38-45 of the instant application are obvious over claims 1, 5, 12-17 and 21 of U.S. Application No. 11/077,813.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

11. No Claims are allowable.

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### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS  
Art unit 1647,  
September 11, 2006.

*Jegatheesan Seharaseyon*  
*Patent Examiner*

14:03 2006

US-10-650-365A-2.rag

GenCore version 5.1.9  
Copyright (c) 1993 - 2006 Bioceleration Ltd.

A - protein search, using sw model

September 1, 2006, 13:18:46 ; Search time 195 Seconds  
(without alignments)  
391.565 Million cell updates/sec

Atle: US-10-650-365A-2  
Perfect score: 861  
Sequence: 1 MCDLPQTHSGNRRALILIA.....EIMRSPSLTNQERLRKE 167

Scoring table: BLOSUM62  
Gapop 10.0 , Gapext 0.5

Searched: 2589679 seqs, 457216429 residues  
Total number of hits satisfying chosen parameters: 2589679

Minimum DB seq length: 0  
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%  
Maximum Match 100%  
Listing first 45 summaries

- Database : A\_Geneseq 8:\*
- 1: Geneseq1980s:\*
  - 2: Geneseq1990s:\*
  - 3: Geneseq2000s:\*
  - 4: Geneseq2001s:\*
  - 5: Geneseq2002s:\*
  - 6: Geneseq2003as:\*
  - 7: Geneseq2003ba:\*
  - 8: Geneseq2004s:\*
  - 9: Geneseq2005s:\*
  - 10: Geneseq2006s:\*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

| Result No. | Score | Query Match | Length | DB ID | Description        |
|------------|-------|-------------|--------|-------|--------------------|
| 1          | 861   | 100.0       | 167    | 2     | AAR11531 Consensus |
| 2          | 861   | 100.0       | 167    | 8     | ADQ87759 rSIFN-co. |
| 3          | 861   | 100.0       | 167    | 8     | ADR97080 Consensus |
| 4          | 861   | 100.0       | 167    | 8     | ADR87295 Consensus |
| 5          | 861   | 100.0       | 167    | 8     | ADW88678 Consensus |
| 6          | 861   | 100.0       | 167    | 9     | ADW59031 Composite |
| 7          | 861   | 100.0       | 167    | 9     | ADZ59356 Interfero |
| 8          | 861   | 100.0       | 167    | 9     | ADZ59356 Recombina |
| 9          | 861   | 100.0       | 167    | 9     | AEB53925 Interfero |
| 10         | 861   | 100.0       | 167    | 10    | AEB61639 Human int |
| 11         | 861   | 100.0       | 167    | 10    | AEB91511 Consensus |
| 12         | 861   | 100.0       | 167    | 10    | AEB91468 Consensus |
| 13         | 856   | 99.4        | 166    | 8     | ADQ32386 Human int |
| 14         | 856   | 99.4        | 166    | 9     | AED67249 Human int |
| 15         | 856   | 99.4        | 189    | 10    | AEB91512 Interfero |
| 16         | 856   | 99.4        | 189    | 10    | AEB91514 Interfero |
| 17         | 856   | 99.4        | 205    | 8     | ADW64375 Human thy |
| 18         | 854   | 99.2        | 167    | 2     | AAR11532 Consensus |
| 19         | 854   | 99.2        | 167    | 8     | ADW69518 Human int |
| 20         | 853   | 99.1        | 166    | 8     | ADW96575 Protein s |
| 21         | 853   | 99.1        | 167    | 8     | ADW69517 Human int |
| 22         | 853   | 99.1        | 170    | 8     | ADW96753 Human alp |
| 23         | 852   | 99.0        | 167    | 2     | AAR11533 Consensus |

|    |       |      |     |    |                     |
|----|-------|------|-----|----|---------------------|
| 24 | 850   | 98.7 | 166 | 1  | AAP30684 Consensus  |
| 25 | 850   | 98.7 | 171 | 7  | ADF47855 Human alp  |
| 26 | 849   | 98.6 | 167 | 8  | ADV69519 Human int  |
| 27 | 847   | 98.4 | 170 | 8  | ADV96755 Human alp  |
| 28 | 845   | 98.1 | 167 | 8  | ADV69520 Human int  |
| 29 | 843   | 97.9 | 166 | 1  | AAP30685 Consensus  |
| 30 | 841   | 97.7 | 166 | 1  | AAP30686 Consensus  |
| 31 | 841   | 97.7 | 170 | 8  | ADV96757 Human alp  |
| 32 | 839.5 | 97.5 | 165 | 8  | ADL88898 Consensus  |
| 33 | 839.5 | 97.5 | 165 | 10 | AEF90856 Consensus  |
| 34 | 839   | 97.4 | 166 | 5  | ABG68838 Interfero  |
| 35 | 831   | 96.5 | 171 | 7  | ADP30369 Recombina  |
| 36 | 826   | 95.9 | 166 | 3  | ABZ8176 Human int   |
| 37 | 824   | 95.7 | 166 | 3  | AAAY44831 Hybrid in |
| 38 | 810   | 94.1 | 166 | 4  | AAG61804 Interfero  |
| 39 | 810   | 94.1 | 166 | 4  | AAG61815 Interfero  |
| 40 | 810   | 94.1 | 166 | 8  | ADI29643 Human int  |
| 41 | 810   | 94.1 | 166 | 8  | ADI29632 Human int  |
| 42 | 808   | 93.8 | 166 | 4  | AAG61818 Interfero  |
| 43 | 808   | 93.8 | 166 | 4  | AAG61826 Interfero  |
| 44 | 808   | 93.8 | 166 | 4  | AAG61795 Interfero  |
| 45 | 808   | 93.8 | 166 | 8  | ADI29623 Human int  |

ALIGNMENTS

RESULT 1  
AAR11531  
ID AAR11531 standard; protein; 167 AA.  
XX AC AAR11531;  
XX AC AAR11531;  
DT 25-MAR-2003 (revised)  
DT 12-JUN-1991 (first entry)  
XX Consensus human leucocyte interferon-alphaF #1.  
XX Interferon; IFN; gene manufacture; anti-viral agent.  
XX Synthetic.  
PN EP422697-A.  
XX PD 17-APR-1991.  
XX PD 25-APR-1983; 90EP-00124236.  
XX PR 06-MAY-1982; 82US-00375494.  
XX PR 15-APR-1983; 83US-00483451.  
(AMGE-) AMGEN.  
Alton NK, Peters MA, Stabinsky Y, Snitman DL;  
WPI; 1991-111234/16.  
N-PSDB; AAQ11283.  
Mfd. structural gene - capable of directing synthesis in a host microorganism of consensus human leukocyte interferon.  
Claim 3; Page 41; 44pp; English.  
This sequence corresponds to the consensus IFN-alphaF analogue [Arg22, Ala76, Asp78, Glu79, Tyr86, Tyr90, Leu96, Thr156, Asn157, Leu158] IFN-alphaF. It is encoded by a manufactured gene which was synthesised from at least two linear subunits using a rapid and highly efficient method. The protein and/or antibodies to them can be labelled for use in assays and/or diagnostic test kits. The protein has antiviral activity. See also AAR11532-3. (Updated on 25-MAR-2003 to correct PF field.)  
Sequence 167 AA;

Query Match 100.0%; Score 861; DB 2; Length 167;  
Best Local Similarity 100.0%; Pred. No. 3.7e-78;  
Matches 167; Conservative 0; Mismatches 0; Indels 0; Gaps 0;  
QY 1 MCDLPQTHSLGNRRALILLAAQMRRIISPPSCLDKRDHDFGFPQEEFDGQFOKQAQISVLHE 60  
DB 1 MCDLPQTHSLGNRRALILLAAQMRRIISPPSCLDKRDHDFGFPQEEFDGQFOKQAQISVLHE 60  
QY 61 MIQOTFNLFSKSSAAWDSLEKFTYLYQQLNDLEACVIEQVGVVEETPLMNVDSILA 120  
DB 61 MIQOTFNLFSKSSAAWDSLEKFTYLYQQLNDLEACVIEQVGVVEETPLMNVDSILA 120  
QY 121 VKKYPQRTITLYLTKKYSFPCAWEVVRAIMRSFSLSTNLQERLRKE 167  
DB 121 VKKYPQRTITLYLTKKYSFPCAWEVVRAIMRSFSLSTNLQERLRKE 167

RESULT 2  
ADQ87759  
ID ADQ87759 standard; protein; 167 AA.  
XX AC ADQ87759;  
DT 09-SEP-2004 (first entry)  
XX RSIFN-co.  
XX recombinant super-compound interferon; rSIFN-co; viral infection; tumour;  
KW hepatitis B; Hepatitis C; hepatitis; Epstein-Barr virus;  
KW Cytomegalovirus; herpes simplex virus; herpes virus; papovavirus;  
KW poxvirus; picornavirus; adenovirus; rhinovirus;  
KW human T cell leukemia virus I; human T cell leukemia virus II;  
KW human T cell leukemia virus III; cancer; skin cancer; liver cancer;  
KW prostate cancer; cervical cancer; Kaposi's sarcoma.  
XX Synthetic.  
XX AU2003248419-A1.  
XX 06-NOV-2003.  
XX 26-SEP-2003; 2003AU-00248419.  
XX 26-SEP-2003; 2003AU-00248419.  
XX (SICH-) SICHUAN BIOTECHNOLOGY RES CENT.  
XX Zhang R, Guo R, Wei G;  
XX WPI; 2004-376455/36.  
XX N-PSDB; ADQ87758.

Novel recombinant super-compound interferon or its functionally equivalent compound with changed spatial configuration, having improved efficacy, is useful for treating tumor or viral diseases e.g. Hepatitis A, Hepatitis B in subject.  
Disclosure; Fig 1; 60pp; English.  
The invention relates to a recombinant super-compound interferon (rSIFN-co) which is functionally equivalent compound with changed spatial configuration, having improved efficacy. rSIFN-co is useful for treating diseases or tumour in a subject, which involves administering rSIFN-co to a subject in need, where the viral diseases is Hepatitis A, Hepatitis C, other types of hepatitis, infections of viruses such as hepatitis A, Cytomegalovirus, herpes simplex viruses, or poxviruses, papovaviruses, poxviruses, picornaviruses, human T cell leukemia viruses I, or human T cell leukemia virus III. rSIFN-co is useful for treating cancer such as skin cancer, liver cancer, prostate cancer, Kaposi's sarcoma. rSIFN-co has improved anti-tumor activity. The present sequence represents the amino

Application wpy  
Appendix A2

XX Sequence 167 AA;  
SQ Query Match 100.0%; Score 861; DB 8; Length 167;  
Best Local Similarity 100.0%; Pred. No. 3.7e-78;  
Matches 167; Conservative 0; Mismatches 0; Indels 0; Gaps 0;  
QY 1 MCDLPQTHSLGNRRALILLAAQMRRIISPPSCLDKRDHDFGFPQEEFDGQFOKQAQISVLHE 60  
DB 1 MCDLPQTHSLGNRRALILLAAQMRRIISPPSCLDKRDHDFGFPQEEFDGQFOKQAQISVLHE 60  
QY 61 MIQOTFNLFSKSSAAWDSLEKFTYLYQQLNDLEACVIEQVGVVEETPLMNVDSILA 120  
DB 61 MIQOTFNLFSKSSAAWDSLEKFTYLYQQLNDLEACVIEQVGVVEETPLMNVDSILA 120  
QY 121 VKKYPQRTITLYLTKKYSFPCAWEVVRAIMRSFSLSTNLQERLRKE 167  
DB 121 VKKYPQRTITLYLTKKYSFPCAWEVVRAIMRSFSLSTNLQERLRKE 167

RESULT 3  
ADR97080  
ID ADR97080 standard; protein; 167 AA.  
XX AC ADR97080;  
DT 02-DEC-2004 (first entry)  
XX Consensus interferon-alpha for treating hepatitis C virus infection.  
DB virucide; hepatitis C virus; infection; interferon-alpha; IFN-alpha;  
KW consensus interferon-alpha; CIPN.  
XX Unidentified.  
XX WO2004078127-A2.  
XX 16-SEP-2004.  
XX 26-FEB-2004; 2004WO-US006218.  
XX 28-FEB-2003; 2003US-0451349P.  
XX (INTE-) INTERMUNE INC.  
XX Blatt LM, Murphy B;  
XX WPI; 2004-668485/65.  
XX Treating hepatitis C virus infection in individual, by administering interferon-alpha to individual by continuous delivery, for 6 weeks.

Disclosure; SEQ ID NO 1; 121pp; English.  
The invention relates to a method of treating (M1) hepatitis C virus infection in individual, by administering interferon (IFN)-alpha to individual by an initial dosage phase (initial serum concentration achieved within 12-48 hours) followed by sustained dosage phase consisting of at least one sustained dosage interval (with first sustained serum concentration of 80-200%, and maintained at steady state for five days), and where the duration of IFN-alpha therapy is at least 6 weeks (M1) is useful for treating hepatitis C virus infection in an individual preferably a human. This sequence corresponds to a consensus interferon-alpha protein used in the method of the invention.

Sequence 167 AA;  
SQ Query Match 100.0%; Score 861; DB 8; Length 167;  
Best Local Similarity 100.0%; Pred. No. 3.7e-78;  
Matches 167; Conservative 0; Mismatches 0; Indels 0; Gaps 0;  
QY 1 MCDLPQTHSLGNRRALILLAAQMRRIISPPSCLDKRDHDFGFPQEEFDGQFOKQAQISVLHE 60  
DB 1 MCDLPQTHSLGNRRALILLAAQMRRIISPPSCLDKRDHDFGFPQEEFDGQFOKQAQISVLHE 60  
QY 61 MIQOTFNLFSKSSAAWDSLEKFTYLYQQLNDLEACVIEQVGVVEETPLMNVDSILA 120  
DB 61 MIQOTFNLFSKSSAAWDSLEKFTYLYQQLNDLEACVIEQVGVVEETPLMNVDSILA 120  
QY 121 VKKYPQRTITLYLTKKYSFPCAWEVVRAIMRSFSLSTNLQERLRKE 167  
DB 121 VKKYPQRTITLYLTKKYSFPCAWEVVRAIMRSFSLSTNLQERLRKE 167